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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|-----------------------------|------------------------|
| 09/716,842 | 11/17/2000 | Roger Briesewitz | STAN-131 | 8224 |
| 24353 7590 02/20/2008 BOZICEVIC, FIELD & FRANCIS LLP 1900 UNIVERSITY AVENUE SUITE 200 EAST PALO ALTO, CA 94303 | | | EXAMINER HUYNH, PHUONG N | |
| | | | ART UNIT 1644 | PAPER NUMBER |
| | | | MAIL DATE 02/20/2008 | DELIVERY MODE PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | | |
|------------------------------|------------------------|--|---------------------|--|
| Office Action Summary | Application No. | | Applicant(s) | |
| | 09/716,842 | | BRIESEWITZ ET AL. | |
| | Examiner | | Art Unit | |
| | Phuong Huynh | | 1644 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE three MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12/12/07.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 16-18,22-26,30-34,36,40-44,46-50 and 52-56 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 16-18,22-26,30-34,36,40-44,46-50 and 52-56 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Claims 16-18, 22-26, 30-34, 36, 40-44, 46-50 and 52-56 are pending.
2. In view of the remand by the Board of Patent Appeals and Interferences, PROSECUTION IS HEREBY REOPENED. A New Office Action is set forth below.
3. The following rejection is based on the recommendation in the Board decision mailed December 12, 2007.
4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office Action:
A person shall be entitled to a patent unless –
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 16-26 and 30-56 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 95/02684 publication (of record, published January 26, 1995; PTO 892).

The WO 98/02684 publication teaches administering to a host animal (see page 10, line 22-25, in particular) a heterodimer ligand comprising FK506 or and FK506-type moiety such as FK520, rapamycin and a CsA or a cyclosporin type moiety (see page 3, lines 1-7, page 34, lines 2-3, page 36, line 1-4, in particular). The publication teaches such ligands are capable of binding to two or more of the receptor domains, i.e., to two or more chimeric proteins containing such receptor domains (see page 4 at lines 6-8, in particular). Examples of such "ligands include those in which the [] moieties are the same or different and comprise an FK506-type moiety, a cyclosporin-type moiety, a steroid or tetracycline" (see page 8, lines 21-23, in particular). The publication teaches a heterodimer comprises FK506 and cyclosporine would have a molecular weight of less than 5000 daltons (see page 33, lines 20-27, page 4, lines 11-12, in particular). The binding of the FK506 conjugate to its receptor FKBP12 inherently modulate the biodistribution of cyclosporine upon administration to the host. The reference FK506 or FK506-type moiety and a CsA or a cyclosporine type moiety are covalently attached to a common linker moiety (see page 34, lines 4, page 37, line 5, Figure 21, in particular) or without a linker moiety (see page 77, line 3, lines 24-25, in particular). The reference targeting domain such as FK506 (peptidyl-proly

isomerase ligand) binds to an endogenous biodistribution modulating protein such as FKBP12 while the cyclosporine (CsA) binds to an endogenous biodistribution modulating protein such as cyclophilin which located in the nucleus (see page 34, lines 6-9, page 26-29, in particular). The reference heterodimer ligand is administered as a pharmaceutical composition to mammal such as a human (see page 10, line 21-25, in particular). Thus, the reference teachings anticipate the claimed invention.

6. No claim is allowed.
7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phuong Huynh, Ph.D. whose telephone number is (571) 272-0846. The examiner can normally be reached Monday through Thursday from 9:00 a.m. to 6:30 p.m. and alternate Friday from 9:00 a.m. to 5:30 p.m. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eileen B O'Hara can be reached on (571) 272-0878. The IFW official Fax number is (571) 273-8300.
8. Any information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Phuong Huynh/

Primary Examiner, Art Unit 1644

February 15, 2008